

**Appl. No.** : 10/070,406  
**Filed** : October 7, 2002

### **REMARKS**

Claims 1-34 are pending in the present application and stand rejected on a variety of grounds. Claims 1-3, 7-9, 11, 13, 15-19, 22, 26-30 and 32-33 are amended herein and claims 20-21 and 31 are cancelled. New claims 35-37 are added. Claim 1 has been amended to clarify the claimed process and to correct a typographical error. Claims 17 and 18 have been amended to recite particular peptides. Support for these amendments can be found, for example, in Example 6 and original claim 28. Claims 1 and 22 have been amended to indicate that the WPI hydrolysate product is water soluble. Support for this amendment can be found, for example, at page 9, lines 10-12 and in Examples 1 and 2. Claims 3, 8-9, 11, 13, 15, 16, 19, 22, 26-30 and 32 have been amended to eliminate multiple dependencies. Claim 19 has been amended to recite administering an effective amount of a WPI hydrolysate produced by the process of claim 1. Support for this amendment can be found, for example, at page 8, lines 30-32. Claim 33 has been amended to adjust the recited group of peptides. No new matter is added by any of the present amendments.

#### Priority

Applicants appreciate the Examiner pointing out that there was an error in their priority claim. In particular, Applicants' claim for priority to New Zealand Application Number 330710, filed June 7, 1998, was an error. However, Applicants note that priority was correctly claimed in the PCT phase and that this application is entitled to a priority date of September 11, 2001, as reflected in the Notice of Acceptance of Application mailed on December 12, 2003. This application is the U.S. National Phase of PCT NZ/01/00188, which in turn claims priority to New Zealand Application Number 506886, filed September 11, 2001. Applicants are in the process of obtaining a replacement declaration that reflects the correct priority information.

#### Claim Objections

Claims 8 and 11-32 were objected to as being in improper form because a multiple dependent claim can only depend from previous claims in the alternative. The present amendments are believed to address the Examiner's concerns.

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Claim Rejections Under 35 U.S.C. §101

Claims 20, 21 and 31 were rejected under 35 U.S.C. §101 because the claimed recitation of a use without setting forth any steps involved in the process results in a claim that is not a proper process claim. Without acquiescing in the rejection, Applicants have cancelled claims 20, 21 and 31.

Claim Rejections Under 35 U.S.C. §112

Claims 1-32 were rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention. In particular, the Examiner found that the recitation “to avoid substantial denaturation of peptides” in claim 1 is indefinite. Without acquiescing in the Examiner’s position, Applicants have amended claim 1 to remove this language.

In addition, the Examiner found that in claim 1 the recitation “wherein the production of the process is highly soluble” is indefinite. As the Examiner recognized, the term “production” is a typographical error. Claim 1 has been amended to replace the term “production” with the term “product.” The Examiner also found that it is not clear what solubility levels are encompassed by the term “highly.” Applicants disagree and submit that in view of the disclosure, one of skill in the art would recognize what is meant by “highly soluble.” Nevertheless, to facilitate prosecution Applicants have amended claim 1 to recite that the product is water soluble. As discussed above, this amendment is fully supported by the specification as filed.

With respect to claim 2, the Examiner found that the claim is confusing because it recites that the enzyme “can be any other heat labile protease,” while claim 1, from which it depends, already requires that the enzyme be a heat labile protease. Claim 2 has been amended to remove this language.

Finally, the Examiner rejected claims 8, 11-32 as indefinite for being improper multiple dependent claims and claims 20, 21 and 31 as indefinite for failing to set forth any process steps. As discussed above, claims 8 and 11-32 have been amended to remove any multiple dependencies and claims 20, 21 and 31 have been cancelled.

For the reasons presented above, Applicants respectfully submit that the rejections under 35 U.S.C. §112 should be withdrawn.

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Claim Rejections Under 35 U.S.C. §102

Claims 1-34 were rejected under 35 U.S.C. §102(b) as anticipated by Schlothauer et al. (WO 99/65326). The Examiner found that “the same enzymes are contacted with the same substrate to achieve the same degree of hydrolysis.” Applicants respectfully submit that this is not the case. To the contrary, the present claims are directed to an improved whey protein hydrolysate prepared from a whey protein isolate (WPI) and not from a whey protein concentrate (WPC). The distinction over Schlothauer et al. is made explicit in the specification at page 3, line 36 through page 4 line 5.

The skilled artisan will appreciate that WPI and WPC are different whey ingredients with a different composition. This distinction is well established in the industry. For the Examiner’s information, Applicants have attached a fact sheet from Dairy Management Inc. detailing some of the differences between WPI and WPC.

Importantly, the present inventors found that unexpectedly, hydrolysates made from WPI had improved properties from those made from WPC. As the specification states beginning at page 3, line 37, “Suprisingly, the use of this different substrate-[WPI] results in a hydrolysate which shows dramatic improvements in the above-mentioned properties of the whey hydrolysates, particularly in the antihypertensive ACE-I inhibiting activity, flavour and functionality of the product.” Detailed support for the unexpected properties of the WPI hydrolysate, including specific comparisons to WPC hydrolysates, can be found throughout the specification, for example in the Summary of the Invention on pages 9-10 and in the Examples beginning on page 12, particularly Example 7.

Schlothauer et al. teaches producing a whey protein hydrolysate from WPC. See, for example, Examples 1 and 2 (pages 8-9). There is no teaching or suggestion in Schlothauer et al. to prepare a hydrolysate from WPI rather than WPC. As claim 1 recites “hydrolyzing a whey protein isolate (WPI)”, Applicants submit that it is not anticipated by Schlothauer et al. Further, as claims 2-16 depend from claim 1 and contain all of the features thereof in addition to further distinguishing features, these claims are also not anticipated by Schlothauer et al.

Claim 17 has been amended to recite a pharmaceutical composition comprising one or more bioactive peptides selected from the group consisting of SAP (SEQ ID NO: 1), VSLPEW (SEQ ID NO: 5), INYWL (SEQ ID NO: 6), LKPTPEGDLEIL (SEQ ID NO: 7) and LKGYGGVSLPEW (SEQ ID NO: 8). As Schlothauer et al. does not disclose any of the recited

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peptides, Applicants submit that claim 17 and dependent claim 18 are not anticipated by this reference.

Claims 19 and 22 both recite a WPI hydrolysate. As Schlothauer et al. has no teaching or suggestion of a WPI hydrolysate, Applicants submit that these independent claims are not anticipated. Dependent claims 23-30 and 32 contain all of the limitations of claim 22 in addition to further distinguishing features and are therefore also not anticipated by Schlothauer et al.

Finally, claims 33 and 34 each recite a bioactive peptide selected from the group consisting SAP (SEQ ID NO: 1), VSLPEW (SEQ ID NO: 5), INYWL (SEQ ID NO: 6), LKPTPEGDLEIL (SEQ ID NO: 7) and LKGYGGVSLPEW (SEQ ID NO: 8). As Schlothauer et al. does not teach or suggest any of these peptide, these claims are also not anticipated.

As Schlothauer et al. does not anticipate any of the claims, Applicants respectfully request withdrawal of this rejection.

Claims 1-34 were also provisionally rejected under 35 U.S.C. §102(e) as anticipated by U.S. Application No. 09/720,041. This application corresponds to the Schlothauer et al. reference and has the same disclosure. Thus, for the reasons presented above Applicants submit that the present claims are not anticipated by this application and request that the rejection be withdrawn.

Claims 1-3, 9, 10, 13-18, 20-23, 26-29 and 31-34 were rejected under 35 U.S.C. §102(b) as anticipated by Mullally et al. (Int. Dairy J. 7:299-303 (1997)). Again, the Examiner found that Mullally anticipates the claims because the same substrate is contacted with the same enzyme under the same conditions. However, as the Examiner recognizes in the Office Action, Mullally discloses a process whereby whey protein concentrate (WPC) is hydrolyzed. Mullally et al. has no teaching of hydrolyzing WPI or suggestion that hydrolyzing WPI would be beneficial. Thus, for the reasons discussed above with respect to Schlothauer et al., Applicants submit that the claims are not anticipated by Mullally et al. and request withdrawal of this rejection.

Claims 1, 2, 7, 13-18, 20-23, 26-29 and 31-34 were also rejected under 35 U.S.C. §102(b) as anticipated by Mellqvist et al. (U.S. Patent No. 4,847,096). As with the other references, the Examiner found that the same substrate is contacted with the same enzyme under the same conditions. However, the Examiner also recognized that Mellqvist discloses a process whereby whey protein concentrate (WPC) is hydrolyzed. Mellqvist has not teaching or suggestion of

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preparing a hydrolysate from WPI. Thus, for the reasons discussed above the claims are not anticipated by Mellqvist and Applicants request withdrawal of the rejection.

#### Claim Rejections Under 35 U.S.C. §103

Claims 1-34 were rejected as unpatentable over the combination of Mullally et al. in view of Abubakar et al. (Tohoku J. Agr. Res. 47:1-8 (1996)). In particular, the Examiner found that Mullally et al. fails to disclose all of the proteases and processing parameters recited in the claims. These deficiencies were found to be made up for by the disclosure in Abubakar et al. along with general knowledge in the art. However, as discussed above, Mullally et al. fails to teach or suggest a hydrolysate prepared from WPI rather than WPC. This deficiency is not made up for by Abubakar et al., which has no teaching of WPI hydrolysates and no suggestion that hydrolysates prepared from WPI would have improved properties. Thus, Applicants request withdrawal of the rejection.

#### Double Patenting

Finally, the Examiner rejected claims 1-34 under the judicially created doctrine of obviousness type double patenting over the claims of co pending application number 09/720,041. The Examiner found that the claims are not patentably distinct because "the processes in the two sets of claims recite contacting essentially the same starting material with the same enzyme." As discussed above, the present claims are directed to WPI hydrolysates, while the claims in the co pending application are directed to hydrolysates prepared from WPC. In this regard, Applicants again note that it is well recognized in the art that WPI and WPC have different compositions and are not "essentially the same material."

As the present claims are directed to patentably distinct subject matter from those in the cited co pending application Applicants request withdrawal of the provisional double patenting rejection.

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**Conclusion**

For the reasons presented above, Applicants respectfully submit that the present application is in condition for allowance and respectfully request the same. If any issues remain, the Examiner is cordially invited to contact Applicants' representative at the number provided below in order to resolve such issues promptly.

Respectfully submitted,

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# Whey Ingredients

## *Sweet Whey, Acid Whey, Whey Protein Concentrates (WPC) and Whey Protein Isolate (WPI)*

Formerly considered a by-product of cheesemaking, whey is now recognized as a "value-added" ingredient because of its highly functional and nutritional properties. Advancements in processing have enabled researchers to improve the functionality and utilization of whey by identifying more concentrated and specialized forms. With many different whey ingredients now available to product developers, new applications continue to evolve.

### *Typical Composition of Dry Sweet and Acid Whey, WPC and WPI*

	Moisture	Protein	Lactose	Fat	Ash
Sweet whey*	3.2	12.9	74.4	1.1	8.4
Acid whey*	3.5	11.7	70.0	0.5	10.8
35% WPC**	4.6	36.2	46.5	2.1	7.8
80% WPC**	4.0	81.0	3.5	7.2	3.1
WPI	3.7	91.5	0.8	0.5	3.7

Source: (\*) Posel, L.P. and Orr, M.L. (1978), (\*\*) Givner, F.A. (1985).

### *Beneficial Features*

Whey, the serum or watery portion of milk that remains after cheesemaking, contains lactose, minerals, vitamins, protein and traces of milkfat. The most valuable component of whey is the protein, which provides both **enhanced functionality and nutrition**. Improved technologies have resulted in whey being consistently processed into customized versions of lactose, whey protein concentrate, and whey protein isolate. This customization translates into product distinction and marketable nutritional benefits.

### *Nutrition*

Whey protein's biological value is high in comparison to that of other dietary proteins, as is its level of essential amino acids. Whey processors have isolated individual whey proteins such as  $\beta$ -lactoglobulin,  $\alpha$ -lactalbumin, lactoferrin and lactoperoxidase for specific nutrient-rich food systems. The individual proteins all have commercial applications.

For example,  $\beta$ -lactoglobulin is used to boost overall protein quality and  $\alpha$ -lactalbumin is used as a protein source for infant formula, while lactoferrin aids infants' iron absorption.

The nonprotein components of whey also have nutritional properties. For example, lactose can increase viscosity and improve the texture of various foods without making them too sweet. It also acts as a balance between carbohydrate and protein in human breast milk replacers based on cows' milk. New developments with lactose have focused on derivatives like galacto-oligosaccharides and lactitol, which is produced by the chemical hydrogenation of lactose and lactulose. When consumed, both of these derivatives are utilized by beneficial colon bacteria, contributing to the well-being of the digestive tract.

### ***Functionality***

WPI, at greater than 90% protein, and WPC, with protein levels ranging from 34% to 90%, are the most functional of all whey ingredients. Functional properties include emulsification, gelation, water-binding, solubility, whipping/foaming and viscosity development. In general, the higher the protein content, the more functional the whey ingredient.

Whey protein conformation and functionality are interrelated and dictated by changes in structure. Functional properties are affected by several factors within a food application including concentration, state of the whey protein, pH, ionic environment, preheat and heat treatments and the presence of lipids.

High solubility over a wide pH range makes WPI and WPC well-suited for sports beverage or meal replacement applications. Water-binding capabilities make them suitable for processed meats, cakes and breads.

### ***DMG*** DAIRY MANAGEMENT INC.

Dairy Management Inc.<sup>TM</sup> (DMI) also supports dairy ingredient uses through the efforts of the Applications Programs. Resources such as technical expertise coupled with the latest pilot plant and facilities enable manufacturers and marketers to solve difficult business challenges. For more information on dairy ingredients and technologies, contact the Technical Support Hotline at 1-800-248-8829 or visit our Web site at [www.doitwithdairy.com](http://www.doitwithdairy.com).



**Do it with dairy.**